



**State of Utah
Department of Commerce**

Division of Occupational and Professional Licensing
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**CLASS B
Nuclear**

INSPECTION

New Opening Regular

INFORMATION

Facility Name: _____ Date: _____

Facility License Number: _____ Expiration Date: _____

Controlled Substance License Number: _____ Expiration Date: _____

DEA Registration Number: _____ Expiration Date: _____

Utah Radioactive Materials License Number: _____ Expiration Date: _____

Facility Email: _____ Facility FEIN Number: _____

Facility Telephone: _____ Facility Fax: _____

Facility Hours (Monday-Friday): _____ (Saturday): _____ (Sunday): _____

Facility Street Address: _____

City: _____ State: _____ Zip: _____

Pharmacist in Charge: _____ Phone Number: _____

Pharmacist in Charge License Number: _____ Expiration Date: _____

PERSONNEL

List ALL individuals authorized to access the pharmacy and administer medication (attach a separate sheet, if necessary):

Name: _____ License Number: _____ Expiration Date: _____



INSPECTION

- | | Yes | No | |
|-----|--------------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | <input type="checkbox"/> | <input type="checkbox"/> | The pharmacy will apply/has applied for and possess a current Utah Radioactive Materials License. [UAC R156-17b-614d] |
| 2. | <input type="checkbox"/> | <input type="checkbox"/> | The pharmacy will/does have adequate space and equipment commensurate with the scope of services required and provided. [UAC R156-17b-614d] |
| 3. | <input type="checkbox"/> | <input type="checkbox"/> | The pharmacy will/does only dispense radiopharmaceuticals that comply with acceptable standards of quality assurance. [UAC R156-17b-614d] |
| 4. | <input type="checkbox"/> | <input type="checkbox"/> | The pharmacy will/does maintain a library commensurate with the level of radiopharmaceutical service to be provided. [UAC R156-17b-614d] |
| 5. | <input type="checkbox"/> | <input type="checkbox"/> | A licensed Utah pharmacist will be/is immediately available on the premises at all times when the facility is open or available to engage in the practice of pharmacy. [UAC R156-17b-614d] |
| 6. | <input type="checkbox"/> | <input type="checkbox"/> | In addition to Utah licensure, the pharmacist shall have classroom and laboratory training and experience as required by the Utah Radiation Control Rules. [UAC R156-17b-614d] |
| 7. | <input type="checkbox"/> | <input type="checkbox"/> | The facility shall be well lighted, ventilated, clean and sanitary. [UAC R156-17b-614] |
| 8. | <input type="checkbox"/> | <input type="checkbox"/> | The dispensing area shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. [UAC R156-17b-614] |
| 9. | <input type="checkbox"/> | <input type="checkbox"/> | The facility shall be equipped to permit the orderly storage of prescription drugs and devices in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614] |
| 10. | <input type="checkbox"/> | <input type="checkbox"/> | The facility shall be equipped with a security system to permit detection of entry at all times when the facility is closed. [UAC R156-17b-614] |
| 11. | <input type="checkbox"/> | <input type="checkbox"/> | The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614] |
| 12. | <input type="checkbox"/> | <input type="checkbox"/> | The temperature of the refrigerator and freezer shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. [UAC R156-17b-614] |
| 13. | <input type="checkbox"/> | <input type="checkbox"/> | Each drug dispensed from the pharmacy shall have a label securely affixed to the container indicating the required minimum information, including the beyond use date. [UCA 58-17b-602] |
| 14. | <input type="checkbox"/> | <input type="checkbox"/> | An annual inventory shall be conducted every 12 months, following an initial inventory, and may be taken within four days of the specified inventory date each year. [UAC R156-17b-614] |
| 15. | <input type="checkbox"/> | <input type="checkbox"/> | The pharmacy does/will maintain a perpetual inventory of all Schedule II controlled substances which is reconciled according to facility policy, is maintained in the pharmacy, and is maintained and listed separately from inventories of any drugs on hand in other areas of a facility. [UAC R156-17b-605 (6)] |
| 16. | <input type="checkbox"/> | <input type="checkbox"/> | The pharmacy will/does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(5)] |
| 17. | <input type="checkbox"/> | <input type="checkbox"/> | The facility shall maintain copy 3 of DEA Order Form 222 which has been properly dated, initialed and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b-614] |
| 18. | <input type="checkbox"/> | <input type="checkbox"/> | The facility has not had any employees who have been terminated or quit due to a loss or suspected loss of any prescription medications. |
| 19. | <input type="checkbox"/> | <input type="checkbox"/> | The facility will be/is engaged in medium or complex compounding activities as defined by USP 35 Chapter 795. If you answer "yes" to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (3))] |



20. Yes No The facility will be/is engaged in low, medium, or high risk *sterile* compounding as defined by USP 35 Chapter 797. If you answer "yes" to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (3))]
21. The facility shall have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel:
- | | |
|--------------------------------------------------------------------------|-------------------------------------------------------------------|
| <input type="checkbox"/> Title 58, Chapter 1 (DOPL Licensing Act) | <input type="checkbox"/> R156-1 (General Rules of DOPL) |
| <input type="checkbox"/> Title 58, Chapter 17b (Pharmacy Practice Act) | <input type="checkbox"/> R156-17b (Pharmacy Practice Act Rules) |
| <input type="checkbox"/> Title 58, Chapter 37 (Controlled Substance Act) | <input type="checkbox"/> R156-37 (Controlled Substance Act Rules) |
| <input type="checkbox"/> Code of Federal Regulations | <input type="checkbox"/> FDA Approved Drug Products (Orange Book) |
| <input type="checkbox"/> General Drug References | <input type="checkbox"/> USP 795 and 797 Compounding Guidebook(s) |
- [UAC R156-17b-614]
22. Facility has a written, properly approved, standard policy and procedure manual. [USP 797]
23. Radiopharmaceuticals prepared as Low-Risk Level compounded sterile preparations with 12-hour or less beyond use date shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment areas shall not cross a line of demarcation into the segregated compounding area. [USP 797]
24. Personnel who prepare compounded sterile preparations (CSPs) are trained by expert personnel, through multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures. Documentation of completion is done before any compounding personnel begin to prepare CSPs. [USP 797]

COMMENTS

(Use an additional sheet if necessary.)



Signature of Pharmacist-in-Charge: _____	Date of Signature: ____ / ____ / ____
Signature of Division Investigator: _____	Date of Signature: ____ / ____ / ____